

REMARKS

These remarks are in response to the Office Action mailed April 21, 2009. In the Office Action dated April 21, 2008, the Examiner had indicated Claim 4 would be allowable if directed to the elected sequence. Applicants believed that this claim is allowable as indicated by the Examiner in the prior Action. Applicants respectfully request clarification.

Claim 1 and 2 have been amended to more clearly set forth the invention. No new matter is believed to have been introduced.

I. PRIORITY

Applicants respectfully submit that the application is entitled to priority of April 1, 2003. The specification of Applicants' priority application discloses information sufficient to demonstrate possession of the claimed invention at least as early as April 1, 2003. One of skill in the art would recognize that Applicants had possession of the claimed sequence by reference to the genomic sequence and protein fragments in combination with the functional and physical characteristics of the disclosure of the encoded polypeptides.

Respectfully, Applicants find it difficult to understand why the priority application lacks support for the sequences based upon a description of a genomic sequence, protein fragments, and functional activity as found in the provisional application. It appears that the Examiner is willing to enable the references cited against the present application while the references lack any indication of (a) a function, (b) a true start or stop or (c) describe the sequences currently claimed by Applicants. Applicants respectfully submit that the Examiner is applying one standard to the cited references and then denying that same standard to Applicants' disclosure.

To explain Applicants' position more clearly, the Examiner cites a genomic sequence of Venter *et al.* as an enabling reference, while simultaneously denying enablement and description of the Applicants' invention based upon a genomic sequence. It is difficult to reconcile the standards being applied. Simply put either both the reference and Applicants' priority application are enabled and provide written description or they both lack enablement and written description.

In addition, the Examiner appears to be willing to grant the skilled person in the art the ability to derive a polypeptide from a partial sequence as set forth in Cocks in view of Meinzel (*i.e.*, to enable and describe Applicants' claimed invention, a requirement for a reference to be prior art) while simultaneously denying Applicants' right to priority using the same skill used to enable the references Cocks in view of Meinzel.

Thus, it is difficult to reconcile the rejections and objections set forth in this, and the previous, office action in view of the different standards that are being applied. In other words, the Examiner is applying two different skill levels to the priority application and to the cited references. Accordingly, Applicants request clarification and withdrawal of the rejection to Applicants priority application or, alternatively, withdrawal of the Venter *et al.* and Cocks references under the rejections below.

II. OBJECTIONS TO THE SPECIFICATION

The Examiner alleges that the specification includes typographical errors associated with the sequence identifiers. Applicants believe that the Examiner is referring to the use of the "ψ" symbol as an indicator of a hydrophobic residue in the sequence. Applicants have amended the paragraphs to remove the use of the greek symbol and replaces with "X"; a standard used in the sequence listing to identify a "feature" in a sequence. If there are other errors the Examiner is respectfully requested to point out the typographical errors with particularity and Applicants will amend the specification appropriately.

III. CLAIM OBJECTIONS

Claims 1, 2 and 5-10 stand objected to for reciting non-elected sequences. Applicants respectfully submit that the sequence of claims 2 and 5-10 are in proper dependent format and further limit the scope of the independent claim; upon allowance of the subject matter of claim 1 the subject matter of claims 2 and 5-10 would be allowable.

IV. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1 and 5-10 stand rejected under 35 U.S.C. §112, second paragraph, because the term “conservative substitutions” allegedly renders the claims indefinite. Applicants respectfully traverse this rejection.

Applicants maintain that the term “conservative substitution” is a well understood term in the art; however, in order to advance prosecution and/or to place the application in better form for appeal, Applicants have deleted reference to “conservative substitutions”. Accordingly, the rejection may be withdrawn.

V. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1 and 7-10 stand rejected under 35 U.S.C. §112, first paragraph as allegedly lacking enablement for the scope of the claimed invention. Applicants respectfully traverse this rejection.

The Examiner agrees that the claims encompass both structure and function. Furthermore, the Examiner agrees that methods of mutagenesis, random mutagenesis etc. are well known. The Examiner further recognizes that methods for testing a protein for the ability to dephosphorylate RNA polymerase II are well known. (see, *e.g.*, the Office Action at 4-5). The Examiner then indicates that in view of these well known techniques and the structure and function recited in the claims there would still be an almost infinite possibility of variants. Applicants respectfully submit that by reciting percent identity with reference to a particular sequence along with a recited function there *cannot* be an almost infinite possibility of variants, but rather a subset that can be easily screened using routine skill as indicated by the Examiner.

The Examiner then goes on to indicate, as discussed more fully below, that Cocks *et al.* and Meinnel *et al.* would be capable of modifying their defective sequence to arrive at Applicants' invention using the same techniques as described above. The Examiner takes the position that Applicants are not enabled but then goes on to indicate that Cocks *et al.* in view of Meinnel *et al.* would be enabled to (i) select one of numerous (almost infinite) polypeptides sequences from Cocks *et al.*, (ii) identify one sequence that would have a stop codon from an almost infinite number of sequences in the correct reading frame (*i.e.*, any length of upstream sequences) and then (iii) insert upstream at one of almost an infinite number of

points a starting methionine. The Examiner appears to indicate that Applicants are not entitled to adding or substituting amino acids having a defined structure and function using routine skill in the art, but Cocks *et al.* in view of Meinnel *et al.* are entitled to random selection of an infinite number of polypeptides to arrive at Applicants' claimed invention having structure but which is not functionally defined to be a kinase. In such instance Cocks *et al.* and Meinnel *et al.* cannot be enabling references as discussed above (*i.e.*, Cocks and Meinnel would fail to be enabling for the same reasons as the Examiner applied to Applicants' priority application) or as further described below. In other words the Examiner "enables" Cocks *et al.* and Meinnel *et al.* yet alleges that Applicants' invention is not enabled.

Applicants respectfully request withdrawal of the present rejection.

VI. REJECTION UNDER 35 U.S.C. §102

Claims 1 and 5-10 stand rejected under §102 as allegedly anticipated by Venter *et al.* (2002). Applicants respectfully traverse this rejection.

Venter *et al.* do not teach Applicants' invention. Venter *et al.* do not teach or suggest a polypeptide having the recited activity as set forth in Applicants' claims. Venter *et al.* do not teach or suggest a polynucleotide that encodes a polypeptide of SEQ ID NO:2.

Furthermore, as the Federal Circuit stated in *In Re Fisher* (Fed. Cir. 2005) a gene sequence without a specific function lacks a specific and substantial utility and the application in question therefore also does not meet the enablement requirement of 35 U.S.C. § 112, as it incorporates the utility requirement of 35 U.S.C. § 101. Accordingly, Applicants submit that Venter *et al.* lacks enablement for a kinase as set forth by Applicants' claimed invention. A non-enabling disclosure is not prior art.

Applicants have amended claim 2, to clarify the sequences as requested by the Examiner at page 5 of the office action. The Examiner indicates that "upon clarification as to what specific sequences are recited in Claim 2, any subsequent rejection under 35 U.S.C. 102(b) or 103(a) will not be considered a new grounds for rejection."

Venter *et al.* do not teach or suggest each and every element of Applicants' claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection.

VII. REJECTION UNDER 35 U.S.C. §103

Claims 1, 3, 4 and 5-10 stands rejected under 35 U.S.C. §103 as allegedly unpatentably over Cocks *et al.* (2003) in view of Meinnel *et al.* (1993). Applicants respectfully traverse this rejection.

The Cocks *et al.* patent is a listing of putative sequence that may or may not have activity, that may or may not have start codons and may or may not have stop codons. SEQ ID NO:843, which is relied upon for the present rejection is a sequence of nearly 2000 base pairs of which only half appear to align. Applicants submit that there is no teaching or suggestion in Cocks *et al.* that identify a sequence set forth by Applicants having the biological activity as set forth in the claims. Cocks *et al.* fail to teach and suggest each and every element of Applicants' claimed invention (*e.g.*, Cocks *et al.* fails to teach the actually sequence and the biological activity encoded by the claimed polynucleotide).

Applicants further submit that Cocks *et al.* is a non-enabling disclosure and lacks a description of Applicants' claimed invention. Applicants, in applying the same standard as what appears to have been applied to Applicants' priority application by the Examiner, could not have arrived at the Applicants' invention based upon the disclosure of Cocks *et al.* (even in view of Meinnel) because any number and length of sequence could have been present at the 5' end of the sequence described by Cocks *et al.* The Examiner infers or assumes that the previous 3 nucleotides would encodes a MET, however, this cannot be assumed or inferred from the teachings of Cocks *et al.*

In order to overcome the deficiencies of Cocks *et al.*, the Office Action combines Meinnel *et al.* for the teaching that nearly all proteins begin with an N-terminal Methionine. Furthermore, Meinnel *et al.* indicates that "most" have such a methionine, clearly then some do not.

As stated above, the Cocks *et al.* disclosure is a non-enabling disclosure for at least two reasons. First, a sequence lacking a functional utility lacks enablement

(see, e.g., *In re Fisher* (Fed. Cir. 2005)). Second, the Examiner attributes enablement only to the extent that a proper start codon is inserted in any number of infinitely possible positions upstream of the sequence identified in Cocks *et al.* For Cocks *et al.* and Meinnel *et al.* to be enabling would required modification of their defective sequence to arrive at Applicants' invention. For Cocks *et al.* in view of Meinnel *et al.* to be enabled one would have to (i) select one of numerous (almost infinite) polypeptides sequences from Cocks *et al.* (i.e., a sequence of any length at the 5' end of the sequence of Cocks *et al.*), (ii) identify one sequence that would have a stop codon from an almost infinite number of sequences in the correct reading frame and then (iii) insert upstream at one of almost an infinite number of points a starting methionine. Even with these feats, the reference would still fail to described a kinase.

The Examiner appears to indicate that Applicants are not entitled to adding or substituting amino acids having a defined structure and function using routine skill in the art, but Cocks *et al.* in view of Meinnel *et al.* are entitled to random selection of an infinite number of polypeptides to arrive at Applicants' claimed invention having structure but which is not functionally defined to be a kinase. Cocks *et al.* in view of Meinnel *et al.* would lack enablement for at least the same reasons that the Examiner indicates for Applicants' invention as claimed or for the purposes of Applicants' priority application. In such instance Cocks *et al.* and Meinnel *et al.* cannot be enabling references as discussed below. Thus, the combination of Cocks *et al.* and Meinnel *et al.* are not enabling and thus cannot be prior art.

Meinnel *et al.* is a general reference that does little to overcome the lack of enablement or description by Cocks *et al.* Rather, Meinnel *et al.* teach only that start codon's are important but does not provide any indication to one of skill in the art a reasonable expectation of any success in generating Applicants' claimed invention based upon the disclosure of Cocks *et al.*

For, at least, the foregoing reasons the claims submitted herewith are non-obvious over the references either alone or in combination.

For at least the foregoing, the Applicant submits that the claimed invention is patentable and request reconsideration and notice of such allowable subject matter.

The Director is authorized to charge any required fee or credit any overpayment to Deposit Account Number 50-4586, please reference the attorney docket number above.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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